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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,273	08/06/2002	Robyn O'Hehir	DAV1154.001 APC	5174

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

NOLAN, PATRICK J

ART UNIT PAPER NUMBER

1644

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,273	O'HEHIR, ROBYN	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,23-33 and 36-42 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-7,23-33,36-39,41 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8-11 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-3-04</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-11, 23-33, 36-40 and newly added claims 41-42 are pending.
2. Applicant's election with traverse of Group I, claims 1-11 and 40-42, species SEQ ID NO. 7 in the reply filed on 6-6-05 is acknowledged. The traversal is on the ground(s) that unity of invention has not been broken. This is not found persuasive because the prior art references still teach Applicant's claimed invention, so Unity of Invention has been properly broken.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 3, 5-7, 23-33, 36-39, 41 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6-6-05.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Slater et al. (reference 6 in the IDS submitted 5-3-04).

Peptide 6 in Figure 2, in Slater et al., is SEQ ID No. 7.

The prior art teachings anticipate the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al., in view of US Patent 4,208,479.

Slater has been discussed supra. In addition Slater teaches that peptide 6 was very useful in immunoassays to determine T cell reactivity in patients allergic to the latex allergen Hev B 5.

The claimed invention differs from the prior art teachings by the recitation of a kit comprising the peptide.

However, the '479 patent specifically teaches that in performing assays it is a matter of substantial convenience, as well as providing significant enhancement in accuracy to provide the reagents in a kit (column, 22 in particular).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time was made to place the peptide taught by Slater et al., in a kit to perform T cell assays since in performing assays it is a matter of substantial convenience, as well as providing significant enhancement in accuracy to provide the reagents in a kit, as taught by the '479 patent.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 4, 8 and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO. 7, does not reasonably provide enablement for derivative, homolog, mutant, chemical equivalent or mimetic of SEQ ID No. 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The recited purpose of SEQ ID NO.7 is to be able interact with T cells, via a MHC-peptide-TcR complex and modify T cell function. Preferably, the peptide is to alter the body immune response to Hev b 5, a known latex allergen. The problem is that once you start changing the amino acid of the MHC peptide binding peptide, it is unpredictable what result you will get. Karin, et al., teaches the a single substitution of alanine for the naturally occurring amino acid at one position in the peptide totally ablates T cell proliferation, but at the very next

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position it significantly enhances disease progression (see Table 1 in particular). It is unknown which positions will generate the desired effect and with which amino acid substitution. Furthermore, Windhagen et al., specifically teaches a single amino acid substitution completely reversed the cytokine profile of a T cell responding to the peptide, a critical consideration t cell peptide therapy of allergy. Since Applicant's T cell peptides are to be used for treatment, and since they have no working examples demonstrating which amino acid substitutions will result in T cell peptides that give the desired effect of treatment of latex allergy, it would be unpredictable and require an undue amount of experimentation to practice the full scope of Applicant's claimed invention.

8. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

August 22nd, 2005